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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,686	10/12/2000	Juha Kononen	4239 55593	2751

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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,686

Applicant(s)

KONONEN ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 and 38-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 26-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-25, drawn to method of making an array.

Group II, claim(s) 26-37, drawn to an apparatus for preparing specimens.

Group III, claim(s) 38-45, drawn to an automated system for making arrays.

Group IV, claim(s) 46-50, drawn to a computer implemented system.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the inventions of Groups I-IV appears to be the array for performing an analysis of biological specimens comprising: donor specimens in a receptacle at fixed assigned locations which locations are maintained and recorded.

However, Battifora et al. (U.S. Patent No. 5,002,377, issued 26 March 1991) teach the array and they teach methods of making the array as recited in instant Claim 1 (Column 2, line 54-Column 3, line 26). Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method for making the array for performing an analysis of biological specimens.

The special technical feature of Group II is considered to be an apparatus for preparing specimens for parallel analysis of sections of biological material arrays.

The special technical feature of Group III is considered to be an automated system for making arrays.

The special technical feature of Group IV is considered to be a computer-implemented system for parallel analysis of consecutive sections of biological arrays.

Accordingly, Groups I-IV are not so linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

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2. During a telephone conversation with Dr. William D. Noonan on 4 December 2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 26-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-15 and 38-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The Provisional Application 60/622,686, filed 25 February 1998 provides adequate support under 35 U.S.C. 112 for claims 26-37 of this application.

It is noted that U.S. Patent No. 6,103,518 filed 5 March 1999 has one inventor in common with the instant Application. The '518 patent discloses a very similar apparatus and claims a species of the instantly claimed apparatus. However, the '518 patent is not prior art because it has a filing date which is later than the instant application.

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Specification

5. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Information Disclosure Statement

6. The references listed on the 1449 of Paper No. 6 and 7 have been reviewed and considered. Additionally, the art cited in the International Search Report has been considered.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 27, 29, 30 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 27 is indefinite for the recitation "the holder comprises an x-y positioning device" because it is unclear whether the recitation refers to the "donor block holder" or the "recipient block holder" of Claim 26. It is suggested that Claim 27 be amended to clarify e.g. before "holder" insert "recipient" (page 8, lines 18-20).

b. Claim 29 is indefinite for the recitation "structures of interest" because "structures" lacks proper antecedent basis in the claim and therefore it is unclear what "structures" are being referenced. It is suggested that Claim 29 be amended to provide proper antecedent basis e.g. after "reference slide" insert "comprising structures" (page 8, lines 25-27).

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c. Claim 29 is indefinite for the recitation "to align structures of interest in the reference slide with corresponding tissue specimens" because "corresponding" is a non-specific relational term and therefore the relationship between the "structures of interest" and "tissue specimens" is undefined. It is suggested that Claim 29 be amended to define the relationship e.g. delete "corresponding" and after "tissue specimen regions" insert "of interest"(page 8, lines 25-27).

d. Claim 30 is indefinite for the recitation "separate reciprocal punch" because it is unclear whether the reciprocal punch is physically separate from the apparatus or separate (i.e. independent) from the reciprocal punch of Claim 26. It is suggested that Claim 30 be amended to clarify e.g. replace "separate" with "second" (page 13, lines 33-34).

e. Claim 36 is indefinite for the recitation "the block" because it is unclear which "block" of Claim 26 is being referenced. It is suggested that Claim 36 be amended to clarify e.g. before "block" insert "recipient".

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 26-30 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by Barrere et al. (U.S. Patent No. 4,684,613, issued 4 August 1987).

Regarding Claim 26, Barrere et al. disclose an apparatus for preparing specimens (i.e. semi-solid media) for parallel analysis of sections of biological material arrays comprising: a donor block holder for holding the donor block; a reciprocal punch positioned in relation to the holder to punch a specimen from the donor block; and a recipient block holder for holding a

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recipient block in a recipient position, wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position in relation to the reciprocal punch to deliver a specimen from the reciprocal punch into the preselected position (Column 2, lines 1-22 and Fig. 1 and 6). Barrere et al. do not teach their donor block holder is "for holding a tissue donor block" and they do not teach their reciprocal punch is "to punch a tissue specimen from the tissue donor block". However, these recitations are functional and do not describe the apparatus in terms of structure. The courts have stated that an apparatus must be distinguished in terms of structure rather than function.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)(see MPEP, § 2114).

Therefore because Barrere et al. disclose the structural limitations of the apparatus, they disclose the apparatus as claimed.

Regarding Claim 27, Barrere et al. disclose the apparatus wherein the holder comprises an x-y positioning device that can be incrementally moved to align sequential receptacles and the reciprocal punch (Column 2, lines 59-64).

Regarding Claim 28, Barrere et al. disclose the apparatus further comprising a stylet positioned for introduction into the reciprocal punch to expel the specimen from the punch into one of the receptacles aligned with the punch (Column 3, lines 5-11 and Fig. 2).

Regarding Claim 29, Barrere et al. disclose the apparatus further comprising a positioner i.e. means for reciprocal movement in mutually perpendicular directions (Column 2, lines 6-8). Barrere et al. do not teach the positioner is "for positioning a reference slide over the donor block" however, the recitation is functional and does not describe the apparatus in terms

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of structural terms. The courts have stated that an apparatus must be distinguished in terms of structure rather than function. Therefore, because Barrere et al. disclose the structural limitations of the apparatus, they disclose the apparatus as claimed.

Regarding Claim 30, Barrere et al. disclose the apparatus further comprising a separate reciprocal punch capable of being positioned relative to the recipient block wherein the separate punch is different that the reciprocal punch i.e. the separate punch is one of the adjacent punches as illustrated in Fig. 3 which is different from the reciprocal punch in that it is located in an adjacent position (Column 2, lines 65-68 and Fig. 3).

Regarding Claim 36, Barrere et al. disclose the apparatus wherein the recipient block comprises an array of spaced biological specimens in a fixed array (Claim 2 and Fig. 1).

11. Claims 26, 28, 30, 34, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Furmanski et al. (U.S. Patent No. 4,914,022, issued 3 April 1990) and as defined by Webster's Ninth New Collegiate Dictionary (Merriam-Webster, Inc. 1991, page 96). The claims are drawn to an apparatus comprising: a donor block; a reciprocal punch; and a recipient block holder. The claims do not recite limitations whereby the apparatus comprises the components are integrated i.e. connected. Webster's Ninth New Collegiate Dictionary defines an "apparatus" as "a set of materials designed for a particular use" (page 96). The claims are given the broadest reasonable interpretation consistent with the claim language, specification and Webster's definition. As such the claims are interpreted as being drawn to an apparatus having components and is not limited to integrated components.

Regarding Claim 26, Furmanski et al. disclose an apparatus for preparing specimens for parallel analysis of sections of biological material comprising: a donor block holder for holding a tissue donor block (i.e. holder mount); a reciprocal punch to punch tissue specimen

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from the tissue donor block (i.e. needle) which can be positioned manually to punch a tissue specimen from the tissue block; and a recipient block holder (i.e. grooved plate) for holding a recipient block wherein the recipient block comprises an array of receptacles (i.e. grooves) each of which are manually positionable to deliver a tissue specimen from the reciprocal punch (Column 3, lines 27-34, Column 4, lines 29-32 and Fig. 1a, and Fig. 1b).

Regarding Claim 28, Furmanski et al. disclose the apparatus further comprising a stylet to expel the tissue specimen from the punch (Column 4, lines 48-52).

Regarding Claim 30, Furmanski et al. disclose the apparatus further comprising a separate (i.e. additional) reciprocal punch capable of being positioned relative to the recipient block (i.e. positioned to mechanically punch a plurality of samples simultaneously) (Column 4, lines 36-40).

Regarding Claim 34, Furmanski et al. disclose the apparatus further comprising a sectioning device for sectioning the recipient block for analysis (Column 6, lines

Regarding Claim 36, Furmanski et al. disclose the recipient block comprises a regular array of spaced biological specimens in fixed assigned locations i.e. the cores are placed at one particular location to aid in examination and when place on the grooved plate, the order is maintained (Column 4, line 64-Column 6 and lines 11-15).

Regarding Claim 37, Furmanski et al. disclose sections produced by the apparatus of Claim 34 (Column 6, lines 51-60 and Fig. 3-4).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrere et al. (U.S. Patent No. 4,684,613, issued 4 August 1987) in view of Bernstein et al. (U.S. Patent No. 5,675,715, issued 7 October 1997).

Regarding Claim 31, Barrere et al. teach an apparatus for preparing specimens (i.e. semi-solid media) for parallel analysis of sections of biological material arrays comprising: a donor block holder for holding the donor block; a reciprocal punch positioned in relation to the holder to punch a specimen from the donor block; and a recipient block holder for holding a recipient block in a recipient position, wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position in relation to the reciprocal punch to deliver a specimen from the reciprocal punch into the preselected position (Column 2, lines 1-22 and Fig. 1 and 6) and they teach the apparatus comprises means for selecting positions and controlling movement (Column 2, lines 21-22) but they do not specifically teach the apparatus comprises a recorder. However, Bernstein et al. teach a similar apparatus comprising holders and means for selecting and controlling movement (Column 4, lines 13-33) wherein the means comprises a recorder recognizes coordinate positions i.e. the recorder records each grid location within the workstation (Column 5, lines 30-50).

Regarding Claim 32, Bernstein et al. teach the apparatus wherein the recording means is a computer implemented system (Column 5, lines 30-35).

Regarding Claim 33, Bernstein et al. teach the apparatus wherein the recorder provides information about the biological material (Column 4, lines 34-48) but they do not teach the information is not obtained from analysis of sections. However, the recitation is functional and does not describe the apparatus in terms of structural terms. The courts have stated that an apparatus must be distinguished in terms of structure rather than function.

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the positioning means of Barrere et al. to further include a computer implemented recorder to coordinate positions of the receptacles to thereby provide an automated apparatus capable of processing a plurality of samples simultaneously for the expected benefit of optimizing sample analysis while minimizing time as taught by Bernstein et al. (Abstract, lines 16-21).

14. Claims 34 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (U.S. Patent No. 5,675,715, issued 7 October 1997) in view of Furmanski et al. (U.S. Patent No. 4,914,022, issued 3 April 1990).

Regarding Claim 34, Barrere et al. teach an apparatus for preparing specimens (i.e. semi-solid media) for parallel analysis of sections of biological material arrays comprising: a donor block holder for holding the donor block; a reciprocal punch positioned in relation to the holder to punch a specimen from the donor block; and a recipient block holder for holding a recipient block in a recipient position, wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position in relation to the reciprocal punch to deliver a specimen from the reciprocal punch into the preselected position (Column 2, lines 1-22 and Fig. 1 and 6) and they teach the apparatus withdraws core samples from semi-solid material (Column 2, lines 1-4) but they do not teach the apparatus further comprises a section device. However, Furmanski et al. teach similar components for preparing specimens comprising a donor block holder for holding a tissue donor block (i.e. holder mount); a reciprocal punch to punch tissue specimen from the tissue donor block (i.e. needle); and a recipient block holder (i.e. grooved plate) for holding a recipient block wherein the recipient block comprises an array of receptacles (i.e. grooves) (Column 3, lines 27-34 and Column 4,

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lines 29-32) and further comprising sectioning device for sectioning the recipient block (Column 6, lines 6-8).

Regarding Claim 37, Furmanski et al. teach recipient block sections (Fig. 2A).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus of Barrere et al. to further include a sectioning device as taught by Furmanski et al. to thereby provide means for sectioning their core samples for microscopic analysis (e.g. detection of antibody-specific binding) for the expected benefit of efficient and rapid analysis sample at the microscopic level as taught by Furmanski et al. (Column 2, lines 8-18)..

15. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein et al. (U.S. Patent No. 5,675,715, issued 7 October 1997) in view of Furmanski et al. (U.S. Patent No. 4,914,022, issued 3 April 1990) as applied to Claim 34 above and further in view of Bernstein et al. (U.S. Patent No. 5,675,715, issued 7 October 1997).

Regarding Claim 35, Barrere et al. teach an apparatus for preparing specimens (i.e. semi-solid media) for parallel analysis of sections of biological material arrays comprising: a donor block holder for holding the donor block; a reciprocal punch positioned in relation to the holder to punch a specimen from the donor block; and a recipient block holder for holding a recipient block in a recipient position, wherein the recipient block comprises an array of receptacles each of which is positionable in a preselected position in relation to the reciprocal punch to deliver a specimen from the reciprocal punch into the preselected position (Column 2, lines 1-22 and Fig. 1 and 6) and they teach the apparatus comprises means for selecting positions and controlling movement (Column 2, lines 21-22) and they teach the apparatus withdraws core samples from semi-solid material (Column 2, lines 1-4) but they do not teach

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the apparatus further comprises a section device. However, Furmanski et al. teach similar components for preparing specimens comprising a donor block holder for holding a tissue donor block (i.e. holder mount); a reciprocal punch to punch tissue specimen from the tissue donor block (i.e. needle); and a recipient block holder (i.e. grooved plate) for holding a recipient block wherein the recipient block comprises an array of receptacles (i.e. grooves) (Column 3, lines 27-34 and Column 4, lines 29-32) and further comprising sectioning device for sectioning the recipient block (Column 6, lines 6-8). Additionally, Barrere et al. teach the apparatus comprises means for selecting positions and controlling movement (Column 2, lines 21-22) but they do not specifically teach the apparatus comprises a recorder. However, Bernstein et al. teach a similar apparatus comprising holders and means for selecting and controlling movement (Column 4, lines 13-33) wherein the means comprises a recorder recognizes coordinate positions i.e. the recorder records each grid location within the workstation (Column 5, lines 30-50). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the positioning means of Barrere et al. to further include a computer implemented recorder to coordinate positions of the receptacles in the apparatus of Barrere et al. and Furmanski et al. to thereby provide an automated apparatus capable of processing a plurality of samples simultaneously for the expected benefit of optimizing sample analysis while minimizing time as taught by Bernstein et al. (Abstract, lines 16-21).

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1655
December 17, 2001